

Food and Drug Administration, HHS

§ 522.82

(1) *Amount.* For average mature mares, 6.0 micrograms per kilogram of body weight.

(2) *Indications for use.* To cause luteolysis in mares with active corpora lutea.

(3) *Limitations.* For intramuscular or subcutaneous use as a single injection. Not for horses intended for food. Alfaprostol is readily absorbed through the skin and can cause abortion and/or bronchial spasms. Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[48 FR 43300, Sept. 23, 1983, as amended at 53 FR 40057, Oct. 13, 1988]

§ 522.56 Amikacin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains 50 milligrams of amikacin (as the sulfate).

(b) *Sponsor.* See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 5 milligrams per pound of body weight twice daily.

(2) *Indications for use.* The drug is used in dogs for treatment of genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli*.

(3) *Limitations.* The drug is administered intramuscularly or subcutaneously. Treat dogs with skin and soft tissue infections for a minimum of 7 days and those with genitourinary infections for 7 to 21 days or until culture is negative and asymptomatic. If no response is observed after 3 days of treatment, therapy should be discontinued and the case re-evaluated. Maximum duration of therapy should not exceed 30 days. Systemic aminoglycoside therapy is contraindicated in dogs with seriously impaired renal function. Not for use in breeding dogs as reproductive studies have not been conducted. Use with extreme caution in dogs in which hearing acuity is required for functioning. Fed-

eral law restricts this drug to use by or on the order of a licensed veterinarian.

[52 FR 11816, Apr. 13, 1987; 52 FR 15412, Apr. 28, 1987, as amended at 53 FR 27851, July 25, 1988; 62 FR 23357, Apr. 30, 1997]

§ 522.62 Aminopentamide hydrogen sulfate injection.

(a) *Chemical name.* 4-(Dimethylamino)-2,2-diphenylvaleramide hydrogen sulfate.

(b) *Specifications.* It is sterile and each milliliter of aqueous solution contains 0.5 milligram of the drug.

(c) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(d) *Conditions of use.* (1) It is intended for use in dogs and cats only for the treatment of vomiting and/or diarrhea, nausea, acute abdominal visceral spasm, pylorospasm, or hypertrophic gastritis.

NOTE: Not for use in animals with glaucoma because of the occurrence of mydriasis.

(2) Dosage is administered by subcutaneous or intramuscular injection every 8 to 12 hours, as follows:

| Weight of animal in pounds | Dosage in milligrams |
|----------------------------|----------------------|
| Up to 10 | 0.1 |
| 11 to 20 | 0.2 |
| 21 to 50 | 0.3 |
| 51 to 100 | 0.4 |
| Over 100 | 0.5 |

Dosage may be gradually increased up to a maximum of five times the suggested dosage. Following parenteral use dosage may be continued by oral administration of tablets.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13858, Mar. 27, 1975, as amended at 53 FR 27851, July 25, 1988]

§ 522.82 Aminopropazine fumarate sterile solution injection.

(a) *Specifications.* Each milliliter of aminopropazine fumarate sterile aqueous solution, veterinary, contains aminopropazine fumarate equivalent to 25 milligrams of aminopropazine base.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for reducing excessive smooth muscle contractions, such as occur in